IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RAS) PRODUCTS LIABILITY LITIGATION	MDL NO. 3094 THIS DOCUMENT RELATES TO ALL CASES JUDGE KAREN SPENCER MARSTON
TAMMYE EDWARDS, Plaintiff, v. Novo Nordisk Inc. and Novo Nordisk A/S, Defendants.	

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff files this Complaint pursuant to the Direct Filing Order and is to be bound by the rights, protections and privileges, and obligations of that Direct Filing Order and other Orders of the Court. Further, in accordance with the Direct Filing Order, Plaintiff hereby designates the United States District Court for the Western District of Louisiana as Plaintiff's designated venue ("Original Venue"). Plaintiff makes this selection based upon one (or more) of the following factors:

__X__ Plaintiff currently resides in Gorum, Louisiana.

__X__ Plaintiff purchased and used Defendant(s)' products in Gorum, Louisiana.

____ The Original Venue is a judicial district in which Defendant _____ resides, and all Defendants are residents of the State in which the district is located (28 USC § 1391(b)(1)).

__X__ The Original Venue is a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred, specifically (28 USC § 1391(b)(2)): Western District of Louisiana.

____There is no district in which an action may otherwise be brought under 28 USC § 1391, and the Original Venue is a judicial district in which Defendant _____ is subject to the Court's personal jurisdiction with respect to this action (28 USC § 1931(b)(3)).

Plaintiff, Tammye Edwards, by Plaintiff's attorneys, Peiffer Wolf Carr Kane Conway & Wise, LP., upon information and belief, at all times hereinafter mentioned, alleges as follows:

NATURE OF THE CASE

1. This is an action for damages suffered by Plaintiff, Tammye Edwards, who was severely injured as a result of Plaintiff's use of Ozempic, injectable prescription medications, respectively, that are used to control blood sugar in adults with type 2 diabetes.

2. Ozempic are also known as semaglutide. Ozempic work by stimulating insulin production and reducing glucose production in the liver helping to lower blood sugar levels.

3. Ozempic belong to a class of drugs called GLP-1 receptor agonists ("GLP-1RAs").

PARTY PLAINTIFF

4. Plaintiff, Tammye Edwards, is a citizen of the United States, and is a resident of the State of Louisiana.

5. Plaintiff is 50 years old.

6. Plaintiff used Ozempic from late January 2023 to January 2024.

7. Plaintiff purchased and used Defendants' products in Gorum, Louisiana.

8. Plaintiff's physician(s) ("prescribing physician(s)") prescribed the Ozempic that was used by Plaintiff.

9. As a result of using Ozempic, Plaintiff was caused to suffer from gastroparesis, causing severe nausea, nausea with vomiting, abdominal discomfort, and constipation, requiring additional medications to alleviate nausea, vomiting, abdominal discomfort, and constipation symptoms.

PARTY DEFENDANTS

10. Defendant Novo Nordisk Inc. is a Delaware corporation with a principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey.

11. Defendant Novo Nordisk A/S is a public limited liability company organized under the laws of Denmark with a principal place of business in Bagsværd, Denmark.

12. Defendants Novo Nordisk Inc. and Novo Nordisk A/S are referred to collectively herein as "Novo Nordisk."

13. Novo Nordisk also designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed Ozempic.

FACTUAL BACKGROUND

A. FDA's Approval of Ozempic

14. On December 5, 2016, Novo Nordisk announced submission of a new drug application (NDA) to the FDA for regulatory approval of once-weekly injectable semaglutide, a new glucagon-like peptide-1 (GLP-1) medication for treatment of type 2 diabetes. In the announcement, Novo Nordisk represented that in clinical trials "once-weekly semaglutide had a safe and well tolerated profile with the most common adverse event being nausea."[1]

15. On December 5, 2016, Defendant Novo Nordisk Inc. submitted NDA 209637, requesting that the FDA grant it approval to market and sell Ozempic (semaglutide) 0.5 mg or 1 mg injection in the United States as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. On December 5, 2017, the FDA approved NDA 209637.[2]

16. On March 20, 2019, Defendant Novo Nordisk Inc. submitted supplemental new drug application (sNDA) 209637/S-003 for Ozempic (semaglutide) 0.5 mg or 1 mg injection, requesting approval to expand its marketing of Ozempic by adding an indication to reduce the risk of major

[1] Novo Nordisk, *Novo Nordisk files for regulatory approval of once-weekly semaglutide in the US and EU for the treatment of type 2 diabetes* (Dec. 5, 2016), available at https://ml.globenewswire.com/Resource/Download/d2f719e1-d69f-4918-ae7e-48fc6b731183 (visited on 9/26/23).

[2] FDA Approval Letter for NDA 209637 (Ozempic), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/209637s000ltr.pdf (visited on 9/26/23).

adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease.[3] On January 16, 2020, the FDA approved sNDA 209637/S-003.[4]

17. On May 28, 2021, Defendant Novo Nordisk Inc. submitted sNDA 209637/S-009, requesting approval for a higher 2 mg dose of Ozempic (semaglutide) injection. On March 28, 2022, the FDA approved sNDA 209637/S-009.[5]

B. Novo Nordisk's Marketing and Promotion of Ozempic

18. On December 5, 2017, Novo Nordisk announced the FDA's approval of Ozempic (semaglutide) 0.5 mg or 1 mg injection in a press release stating that: "Novo Nordisk expects to launch OZEMPIC® in the U.S. in Q1 2018, with a goal of ensuring broad insurance coverage and patient access to the product. OZEMPIC® will be priced at parity to current market-leading weekly GLP-1RAs and will be offered with a savings card program to reduce co-pays for eligible commercially insured patients. Additionally, as part of the access strategy, Novo Nordisk is working with appropriate health insurance providers to establish innovative contracting solutions."[6]

19. On February 5, 2018, Novo Nordisk announced that it had started selling Ozempic in the United States and touted the medication as a "new treatment option[]" that "addresses the concerns and needs of people with diabetes[.]" Novo Nordisk offered an "Instant Savings Card to reduce co-pays to as low as $25 per prescription fill for up to two years."[7]

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[3] *Novo Nordisk files for US FDA approval of oral semaglutide for blood sugar control and cardiovascular risk reduction in adults with type 2 diabetes*, Cision PR Newswire (March 20, 2019), available at https://www.prnewswire.com/news-releases/novo-nordisk-files-for-us-fda-approval-of-oral-semaglutide-for-blood-sugar-control-and-cardiovascular-risk-reduction-in-adults-with-type-2-diabetes-300815668.html (visited on 9/26/23).

[4] FDA Supplement Approval Letter for NDA 209637/A-003 (Ozempic), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/209637Orig1s003ltr.pdf (visited on 9/26/23).

[5] FDA Supplement Approval Letter for NDA 209637/S-009 (Ozempic), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/209637Orig1s009ltr.pdf (visited on 9/26/23).

[6] *Novo Nordisk Receives FDA Approval of OZEMPIC® (semaglutide) Injection For the Treatment of Adults with Type 2 Diabetes*, Cision PR Newswire (December 05, 2017), available at https://www.prnewswire.com/news-releases/novo-nordisk-receives-fda-approval-of-ozempic-semaglutide-injection- for-the-treatment-of-adults-with-type-2-diabetes-300567052.html (visited on 9/26/23).

[7] *Novo Nordisk Launches Ozempic® and Fiasp®, Expanding Treatment Options for Adults with Diabetes*, Cision PR Newswire (February 05, 2018), available at

20. Novo Nordisk promoted the safety and sale of Ozempic in the United States on its websites, in press releases, through in-person presentations, through the drug's label, in print materials, on social media, and through other public outlets.

21. On July 30, 2018, Novo Nordisk launched its first television ad for Ozempic, to the tune of the 1970s hit pop song "Magic" by Pilot, wherein Novo Nordisk advertised that "adults lost on average up to 12 pounds" when taking Ozempic, even though it is not indicated for weight loss[8]

22. On March 28, 2022, Novo Nordisk announced the FDA's approval of sNDA 209637/S-009 for a higher 2 mg dose of Ozempic (semaglutide) injection. In the press release, Novo Nordisk represented Ozempic as having "proven safety" and advertised that "plus it can help many patients lose some weight."[9]

23. Since 2018, Novo Nordisk has spent more than $884,000,000 on television ads in the United States to promote its semaglutide drugs (Ozempic, Wegovy and Rybelsus) with the majority of the spending allocated specifically to advertising Ozempic.[10]

24. In 2022, Novo Nordisk spent $180.2 million on Ozempic ads, including an estimated $157 million on national television ads for Ozempic, making Ozempic the sixth most advertised drug that year. As a result of its GLP-1RA treatments, including Ozempic, Novo Nordisk forecasts sales growth of 13% to 19% for 2023.[11]

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https://www.prnewswire.com/news-releases/novo-nordisk-launches-ozempic-and-fiasp-expanding-treatment- options-for-adults-with-diabetes-300592808.html (visited on 9/26/23).

[8] *Ozempic TV Spot, 'Oh!'*, iSpot.tv (July 30, 2018), available at https://www.ispot.tv/ad/d6Xz/ozempic-oh (visited on 9/26/23).

[9] *Novo Nordisk receives FDA approval of higher-dose Ozempic® 2 mg providing increased glycemic control for adults with type 2 diabetes*, Cision PR Newswire (March 28, 2022), available at https://www.prnewswire.com/news-releases/novo-nordisk-receives-fda-approval-of-higher-dose-ozempic-2-mg- providing-increased-glycemic-control-for-adults-with-type-2-diabetes-301512209.html (visited on 10/16/23).

[10] Ritzau, *Novo Nordisk runs TV ads in US for multimillion-dollar sum*, MedWatch (April 26, 2023), available at https://medwatch.com/News/Pharma_____Biotech/article15680727.ece (visited on 9/26/23).

[11] Adams B, Fierce Pharma, *The top 10 pharma drug ad spenders for 2022*, https://www.fiercepharma.com/special-reports/top-10-pharma-drug-brand-ad-spenders-2022 (visited on 9/26/23).

25. On July 6, 2023, it was reported that Novo Nordisk had spent $11 million in 2022 on food and travel for doctors "as part of its push to promote Ozempic and other weight loss- inducing diabetes drugs."[12] The spending bought more than 457,000 meals for almost 12,000 doctors while also flying doctors to places like London, Paris, Orlando, and Honolulu.[13]

26. In an article published on July 21, 2023, the President and CEO of the Alliance of Community Health Plans described Novo Nordisk's spending on meals for doctors as "outrageous" and suggested that the millions Novo Nordisk spent marketing its drugs to prescribers would be better used furthering research about potential side effects and long-term effectiveness. The author cited research published in the spring of 2023 showing an increased risk of intestinal obstruction as a result of using GLP-1RA drugs.[14]

27. As a result of Novo Nordisk's advertising and promotion efforts, Ozempic has been widely used throughout the United States. The number of prescriptions filled reached an all-time high of 373,000 in one week in February of 2023, with more than half of those being new prescriptions.[15] In June 2023, it was reported that new prescriptions for Ozempic had surged by 140 percent from the prior year.[16]

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[12] Nicolas Florko, *Novo Nordisk bought prescribers over 450,000 meals and snacks to promote drugs like Ozempic*, National Center for Health Research (July 5, 2023), available at https://www.center4research.org/novo-nordisk- gave-doctors-450000-meals-ozempic/ (visited on 9/26/23).

[13] *Id*.

[14] Erin Prater, *Ozempic manufacturer Novo Nordisk spent $11 million last year 'wining and dining' doctors. Experts slam the move as a breach of doctor-patient trust,* Fortune Well (July 21, 2023), available at https://fortune.com/well/2023/07/21/ozempic-novo-nordisk-meals-travel-prescribing-doctors/ (visited on 9/26/23); *see also* Erin Prater, *Weight-loss drugs like Ozempic and Wegovy may put certain people at risk of serious complications, researchers warn*, Fortune Well (March 7, 2023), available at https://fortune.com/well/2023/03/07/ozempic-wegovy-elevated-risk-intestinal-obstruction-later-type-2-diabetes- weight-loss-drug/ (visited on 10/18/23).

[15] Choi A, Vu H, *Ozempic prescriptions can be easy to get online. Its popularity for weight loss is hurting those who need it most*, CNN (March 17, 2023), available at https://www.cnn.com/2023/03/17/health/ozempic-shortage-tiktok-telehealth/ (visited on 9/26/23).

[16] Gilbert D, *Insurers clamping down on doctors who prescribe Ozempic for weight loss*, The Washington Post (June 12, 2023), available at https://www.washingtonpost.com/business/2023/06/11/weight-loss-ozempic-wegovy- insurance/ (visited on 9/26/23).

28. On TikTok, the hashtag #Ozempic had 273 million views as of November 22, 2022,[17] and currently has over 1.3 billion views.[18]

29. On June 15, 2023, NBC News published a report about the "thousands of weight-loss ads on social media for the drugs Ozempic and Wegovy." While many of those ads were found to be from online pharmacies, medical spas, and diet clinics, as of June of 2023, Novo Nordisk was still running online social-media ads for its semaglutide products, despite claiming in May that it would stop running ads due to a shortage of the drug.[19]

30. On July 10, 2023, a global media company declared Ozempic as "2023's buzziest drug" and one of the "Hottest Brands, disrupting U.S. culture and industry."[20]

31. At all relevant times, Novo Nordisk was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute Ozempic.

C. Plaintiff's Injuries

32. GLP-1 RAs can cause a myriad of injuries including: developing gastroparesis; gastroparesis requiring hospitalization or emergency care; refractory gastroparesis potentially leading to debilitating secondary conditions such as Wernicke's encephalopathy; gastroenteritis; cyclical vomiting; bowel/intestinal obstruction/blockage; ileus; ischemic bowel, DVT and associated pulmonary embolism ("PE"); gallbladder conditions necessitating surgery; esophageal injury; bowel injury; intraoperative aspiration; muscle wasting; vitamin deficiencies, including micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12;

[17] Blum D, *What is Ozempic and Why Is It Getting So Much Attention?,* The New York Times (published Nov. 22, 2022, updated July 24, 2023), available at https://www.nytimes.com/2022/11/22/well/ozempic-diabetes-weight-loss.html (visited on 9/26/23).

[18] https://www.tiktok.com/tag/ozempic (visited on 11/14/23).

[19] Ingram D, *More than 4,000 ads for Ozempic-style drugs found running on Instagram and Facebook*, NBC News (June 15, 2023), available at https://www.nbcnews.com/tech/internet/ozempic-weight-loss-drug-ads-instagram-wegovy-semaglutide-rcna88602 (visited on 9/26/23).

[20] Bain P, *Ozempic was 2023's Buzziest Drug*, AdAge (July 10, 2023), available at https://adage.com/article/special-report-hottest-brands/ozempic-hottest-brands-most-popular-marketing-2023/2500571 (visited on 9/26/23).

hypovitaminosis.

33. These injuries can be debilitating and go so far as to result in death. The FDA adverse events database lists nearly 500 deaths related to semaglutide (Novo's GLP-1 RA) in the United States.[21] Recent reports indicate that a British nurse, Susan McGowan, aged 58, passed away from "multiple organ failure, septic shock . . . pancreatitis . . . and "the use of prescribed tirzepatide" (Lilly's GLP-1 RA).[22] In the United Kingdom, there have been at least 23 deaths linked to semaglutide since 2019.[23]

1. Gastrointestinal Injuries

34. Gastrointestinal adverse events are well known side effects of the GLP-1 RA class of drugs, as Defendants have acknowledged,[24] but Defendants have downplayed the chronic nature, duration and severity of gastrointestinal injuries caused by their GLP-1 RAs. Many Plaintiffs in this case have experienced debilitating, long-lasting effects, such as vomiting week after week (i.e., unremitting or cyclical vomiting), and for many Plaintiffs, even after being hospitalized and discharged, the effects of life-altering treatment, such as replacement of their colon with a colostomy bag,[25] persist. In addition, many Plaintiffs have experienced adverse events for which Defendants failed to provide any warning.

34. These gastrointestinal injuries caused by GLP-1 RAs can lead to life threatening and long-term consequences, including hospitalization, esophageal tearing, ischemia and necrosis in the digestive tract, bowel perforation, sepsis, bowel resection, colostomy, perioperative aspiration, dehydration, micronutrient deficiency, disability, and death.

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[21] https://www.cnn.com/2024/11/06/health/compounded-semaglutide-deaths-novo-nordisk- ceo/index.html (last visited 11/10/2024).

[22] MacPhee and Cheyne, *Nurse's death linked to approved weight-loss drug*, https://www.bbc.com/news/articles/cz6jg6nw2zeo (last visited 11/10/2024).

[23] *Id*.

[24] *See, e.g.*, Jones, *Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell"*, Rolling Stone (July 25, 2023), available at https://www.rollingstone.com/culture/culture- news/ozempic-stomach-paralysis-weight-loss-side-effects-1234794601.

[25] A colostomy bag collects stool. It is attached to the body through a surgical procedure called a colostomy that changes the way that stool exits the body. When medical reasons (such as a removal of part of the bowel) require the colon to be bypassed, surgeons make a new opening in the abdominal wall for stool to come out.

a. Gastroparesis

35. Gastroparesis is the slowing or halting of transit of food from the stomach to the intestines in the absence of a physical obstruction. Common symptoms of gastroparesis include nausea, vomiting, abdominal bloating, early satiety, and abdominal pain or discomfort. Moderate cases of gastroparesis often require acute or emergency care and treatment while more debilitating cases of gastroparesis can require hospitalization.[26] During normal gastric emptying, food passes quickly from the stomach. Muscles surrounding the stomach contract to move solid food through the pyloric sphincter and out of the stomach. However, with gastroparesis, the digestive muscles surrounding the stomach move more slowly and weakly and the pyloric sphincter remains closed, causing solid food to remain in the stomach for extended periods.[27] Gastroparesis can interfere with normal digestion and cause nausea, vomiting (including vomiting of undigested food), abdominal pain, abdominal bloating, severe dehydration, a feeling of fullness after eating just a few bites, undigested food hardening and remaining in the stomach, acid reflux, changes in blood sugar levels, lack of appetite, weight loss, and a decreased quality of life.

36. GLP-1 RA-induced gastroparesis is persistent, and for many Plaintiffs, symptoms continue for weeks following cessation of GLP-1 RAs. In some cases, gastroparesis leads to secondary conditions which may never be resolved, such as Wernicke's encephalopathy.

37. There are no good treatments for gastroparesis. Treatment often depends upon the severity of the symptoms. While many cases of gastroparesis require correcting fluid, electrolyte, and nutritional deficiencies, reducing symptoms, and identifying the underlying cause; other cases require treatment with the drug Metoclopramide. Metoclopramide is the only medicine the FDA has approved for the treatment of gastroparesis. The Metoclopramide pill has a risk of serious side effects.

[26] Henry P. Parkman, *American Gastroenterological Association Technical Review on the Diagnosis and Treatment of Gastroparesis,* Gastroenterology (Nov. 2004).
[27] *See id.*

38. The most serious cases of gastroparesis may leave patients unable to have any food or liquids. These individuals may require a feeding tube called a jejunostomy to be placed in the small intestines, or a gastric venting tube to be inserted to help relieve pressure from gastric contents.

39. Gastric electrical stimulation is another tool for the treatment of gastroparesis. In gastric electrical stimulation, a device is implanted into the body to provide electrical stimulation to the stomach muscles to improve gastric motility.

40. In a 2004 review of gastroparesis published by the American Gastroenterological Association, the authors recommended that treating physicians should review the medications of patients experiencing gastroparesis in order to "eliminate drugs that might exacerbate the underlying dysmotility disorder."[28] Thus, it is important for clinicians to know whether a drug can induce or contribute to gastroparesis.

41. Treatment of more debilitating gastroparesis can include the prescription of medications with serious side effects.

42. When gastroparesis does not resolve after cessation of GLP-1 RAs, further treatment options are limited and undesirable, with each carrying its own significant risks. The only medicine approved by the FDA to treat gastroparesis, metoclopramide, has risks of serious side effects,[29] including a permanent movement disorder called tardive dyskinesia, and is recommended only for short term use of 12 weeks or less.[30] For patients whose gastroparesis is debilitating enough to prevent them from consuming food or liquids, a feeding tube called a jejunostomy tube placed in the small intestine, or a gastric venting tube to help relieve pressure from gastric contents, may be

[28] *See id.*

[29] Mayo Clinic, *Gastroparesis* (Sept. 6, 2024), available at https://www.mayoclinic.org/diseases-conditions/gastroparesis/diagnosis-treatment/drc-20355792.

[30] Mayo Clinic, *Metoclopramide (oral route)* (Feb. 1, 2024), available at https://www.mayoclinic.org/drugs-supplements/metoclopramide-oral-route/description/drg- 20064784.

necessary.[31]

FIRST CAUSE OF ACTION
(INADEQUATE WARNING—AGAINST ALL DEFENDANTS)

43. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

44. Kentucky law imposes a duty on producers, manufacturers, distributors, lessors, and sellers of a product to exercise all reasonable care when producing, manufacturing, distributing, leasing, and selling their products.

45. At all times mentioned herein, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed the Ozempic that were used by Plaintiff.

46. Ozempic were expected to and did reach the usual consumers, handlers, and persons coming into contact with said products without substantial change in the condition in which they were produced, manufactured, sold, distributed, and marketed by Defendants.

47. At all relevant times, and at the times Ozempic left Defendants' control, Defendants knew or should have known that Ozempic were unreasonably dangerous because they did not adequately warn of the risk of ileus, intestinal obstruction, and their sequelae, especially when used in the form and manner as provided by Defendants.

48. Despite the fact that Defendants knew or should have known that Ozempic caused unreasonably dangerous injuries, Defendants continued to market, distribute, and/or sell Ozempic to consumers, including Plaintiff, without adequate warnings.

49. Despite the fact that Defendants knew or should have known that Ozempic caused

[31] Mayo Clinic, *Gastroparesis* (Sept. 6, 2024), available at https://www.mayoclinic.org/diseases-conditions/gastroparesis/diagnosis-treatment/drc-20355792.

unreasonably dangerous injuries, Defendants continued to market Ozempic to prescribing physicians, including Plaintiff's prescribing physician(s), without adequate warnings.

50. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of their failure to provide adequate warnings, as set forth herein.

51. At all relevant times, given their increased safety risks, Ozempic were not fit for the ordinary purpose for which they were intended.

52. At all relevant times, given their increased safety risks, Ozempic did not meet the reasonable expectations of an ordinary consumer, particularly Plaintiff.

53. Defendants had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, sale, and/or distribution of Ozempic into the stream of commerce, including a duty to assure that the products would not cause users to suffer unreasonable, dangerous injuries, such as ileus, intestinal obstruction, and their sequelae.

54. At all relevant times, Plaintiff were using Ozempic in a reasonably foreseeable manner, for the purposes normally intended.

55. The Ozempic designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective due to inadequate warnings or instructions, as Defendants knew or should have known that the products created risks of serious and dangerous injuries, including ileus, intestinal obstruction, and their sequelae, as well as other severe and personal injuries which are permanent and lasting in nature, and Defendants failed to adequately warn of said risks.

56. The Ozempic designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants were defective due to inadequate post- marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of

serious side effects, including ileus, intestinal obstruction, and their sequalae, as well as other severe and permanent health consequences from Ozempic, they failed to provide adequate warnings to users and/or prescribers of the products, and continued to improperly advertise, market and/or promote their products, Ozempic.

57. The labels for Ozempic were inadequate because they did not warn and/or adequately warn of all possible adverse side effects causally associated with the use of Ozempic, including the increased risk of ileus, intestinal obstruction, and their sequelae.

58. The labels for Ozempic were inadequate because they did not warn and/or adequately warn that Ozempic had not been sufficiently and/or adequately tested for safety risks, including ileus, intestinal obstruction, and their sequelae.

59. The labels for Ozempic were inadequate because they did not warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of Ozempic.

60. The labels for Ozempic were inadequate because they did not warn and/or adequately warn of the severity and duration of adverse effects, as the warnings given did not accurately reflect the symptoms or severity of the side effects.

61. Communications made by Defendants to Plaintiff and Plaintiff's prescribing physician(s) were inadequate because Defendants failed to warn and/or adequately warn of all possible adverse side effects causally associated with the use of Ozempic, including the increased risk of ileus, intestinal obstruction, and their sequelae.

62. Communications made by Defendants to Plaintiff and Plaintiff's prescribing physician(s) were inadequate because Defendants failed to warn and/or adequately warn that Ozempic had not been sufficiently and/or adequately tested for safety risks, including ileus, intestinal obstruction, and their sequelae.

63. Plaintiff had no way to determine the truth behind the inadequacies of Defendants'

warnings as identified herein, and Plaintiff's reliance upon Defendants' warnings was reasonable.

64. Plaintiff's prescribing physician(s) had no way to determine the truth behind the inadequacies of Defendants' warnings as identified herein, and his/her/their reliance upon Defendants' warnings was reasonable.

65. Defendants knew or should have known that neither Plaintiff nor Plaintiff's prescribing physicians would realize the danger of ileus, intestinal obstruction, and their sequelae caused by Ozempic.

66. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risks of ileus, intestinal obstruction, and their sequalae, which are causally associated with Ozempic, then the prescribing physician would not have prescribed Ozempic and/or would have provided Plaintiff with adequate warnings regarding the dangers of Ozempic so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic.

67. Upon information and belief, had Plaintiff's prescribing physician(s) been warned that Ozempic had not been sufficiently and/or adequately tested for safety risks, including ileus, intestinal obstruction, and their sequelae, the prescribing physician would not have prescribed Ozempic and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Ozempic so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic.

68. If Plaintiff had been warned of the increased risks of ileus, intestinal obstruction, and their sequelae, which are causally associated with Ozempic, then Plaintiff would have informed Plaintiff's prescribers that Plaintiff did not want to take Ozempic.

69. Upon information and belief, if Plaintiff had informed Plaintiff's prescribing physician(s) that Plaintiff did not want to take Ozempic due to the risks of ileus, intestinal obstruction, and their sequelae, or the lack of adequate testing for safety risks, then Plaintiff's prescribing

physician(s) would not have prescribed Ozempic.

70. Because of the foregoing, Defendants have become liable to Plaintiff for designing, marketing, promoting, distribution and/or selling of unreasonably dangerous products, Ozempic.

71. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed defective products which created unreasonable risks to the health of consumers and to Plaintiff in particular, and Defendants are therefore liable for the injuries sustained by Plaintiff.

72. Defendants' inadequate warnings for Ozempic were acts that amount to willful, wanton, and/or reckless conducts by Defendants.

73. Said inadequate warnings for Defendants' drugs Ozempic were a substantial factor in causing Plaintiff's injuries.

74. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous injuries, including ileus, intestinal obstruction, and their sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

75. As a result of the foregoing acts and omissions Plaintiff did incur medical, health, incidental, and related expenses, and requires and/or will require more health care and services. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

SECOND CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION-AGAINST ALL DEFENDANTS)

76. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully

set forth herein.

77. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Ozempic, which were used by Plaintiff as hereinabove described.

78. At all relevant times, Defendants knew or should have known that Ozempic has not been adequately and/or sufficiently tested for safety.

79. At all relevant times, Defendants knew or should have known of the serious side effects of Ozempic, including ileus, intestinal obstruction, and their sequelae.

80. Defendants had a duty to disclose material information about Ozempic to Plaintiff and Plaintiff's prescribing physician(s) that Ozempic are causally associated with increased risk of ileus, intestinal obstruction, and their sequelae, because Defendants held a special expertise with respect to Ozempic, Plaintiff, as a user of Ozempic, had a special relationship of trust with Defendants, and Defendants knew that their statements regarding the risks causally associated with Ozempic would be relied on by Ozempic users.

81. Nonetheless, Defendants made material misrepresentations to Plaintiff, Plaintiff's prescribing physician(s), the medical and healthcare community at large, and the general public regarding the safety and/or efficacy of Ozempic.

82. Defendants represented affirmatively and by omission on television advertisements and on the labels of Ozempic that Ozempic were safe and effective drugs for treatment of adults with type 2 diabetes, despite being aware of increased risks of ileus, intestinal obstruction, and their sequelae causally associated with using Ozempic.

83. Defendants were aware or should have been aware that their representations were false or misleading and knew that they were concealing and/or omitting material information from Plaintiff, Plaintiff's prescribing physician(s), the medical and healthcare community, and the general

public.

84. Defendants knew that Plaintiff and Plaintiff's prescribing physicians (s) had no way to determine the truth behind Defendants' misrepresentations and concealments surrounding Ozempic, as set forth herein.

85. Upon information and belief that Plaintiff's prescribing physician(s) justifiably relied on Defendants' material misrepresentations, including the omissions contained therein, when making the decision to prescribe Ozempic to Plaintiff.

86. Upon information and belief, had Plaintiff's prescribing physician(s) been informed of the increased risk of ileus, intestinal obstruction, and their sequelae causally associated with Ozempic, Plaintiff's prescribing physician(s) would not have prescribed Ozempic and/or would have provided Plaintiff with adequate information regarding safety of Ozempic to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic.

87. Upon information and belief, had Plaintiff's prescribing physician(s) been told that Ozempic had not been sufficiently and/or adequately tested for safety risks, including ileus, intestinal obstruction, and their sequelae, they would not have prescribed Ozempic and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Ozempic so that Plaintiff can make an informed decision regarding Plaintiff's use of Ozempic.

88. Plaintiff reasonably relied on the false and/or misleading facts and information disseminated by Defendants, which included Defendants' omissions of material facts in which Plaintiff had no way to know were omitted.

89. Had Plaintiff been told of the increased risk of ileus, intestinal obstruction, and their sequelae causally associated with Ozempic, Plaintiff would not have used Ozempic and/or suffered ileus, intestinal obstruction, and their sequelae.

90. Defendants' misrepresentations and omissions of material facts amount to willful,

wanton, and/or reckless conduct.

91. As a direct and proximate result of the above stated false representations and/or omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries including ileus, intestinal obstruction, and their sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

92. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

THIRD CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION —AGAINST ALL DEFENDANTS)

93. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

94. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Ozempic, which were used by Plaintiff as hereinabove described.

95. At all relevant times, Defendants knew or should have known that Ozempic had not been adequately and/or sufficiently tested for safety.

96. At all relevant times, Defendants knew or should have known of the serious side effects of Ozempic, including ileus, intestinal obstruction, and their sequelae.

97. At all relevant times, Defendants knew or should have known that Ozempic were not safe to improve glycemic control in adults with type 2 diabetes, reduce cardiovascular risk in patients

with type 2 diabetes, or promote weight loss, given their increased risks of ileus, intestinal obstruction, and their sequelae.

98. Nonetheless, Defendants made material misrepresentations to Plaintiff, Plaintiff's prescribing physician(s), the medical and healthcare community at large, and the general public regarding the safety and/or efficacy of Ozempic.

99. Defendants represented affirmatively and by omission on television advertisements and on the labels of Ozempic that Ozempic were safe and effective drugs for treatment of adults with type 2 diabetes, despite being aware of increased risks of ileus, intestinal obstruction, and their sequelae causally associated with using Ozempic.

100. Defendants were aware or should have been aware that their representations were false or misleading and knew that they were concealing and/or omitting material information from Plaintiff, Plaintiff's prescribing physician(s), the medical and healthcare community, and the general public.

101. Defendants' misrepresentations of material facts were made purposefully, willfully, wantonly, and/or recklessly in order to mislead and induce medical and healthcare providers, such as Plaintiff's prescribing physician(s), and adult type 2 diabetes patients, such as Plaintiff, to dispense, provide, prescribe, accept, purchase, and/or consume Ozempic for treatment of type 2 diabetes.

102. Upon information and belief that Plaintiff's prescribing physician(s) had no way to determine the truth behind Defendants' false and/or misleading statements, concealments and omissions surrounding Ozempic and reasonably relied on false and/or misleading facts and information disseminated by Defendants, which included Defendants' omissions of material facts in which Plaintiff's prescribing physician(s) had no way to know were omitted.

103. Upon information and belief that Plaintiff's prescribing physician(s) justifiably relied on Defendants' material misrepresentations, including the omissions contained therein, when making

the decision to prescribe Ozempic to Plaintiff.

104. Upon information and belief, had Plaintiff's prescribing physician(s) been told that Ozempic had not been sufficiently and/or adequately tested for safety risks, including ileus, intestinal obstruction, and their sequelae, they would not have prescribed Ozempic and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Ozempic so that Plaintiff can make an informed decision regarding Plaintiff's use of Ozempic.

105. Plaintiff had no way to determine the truth behind Defendant's false and/or misleading statements, concealments and omissions surrounding Ozempic, and reasonably relied on false and/or misleading facts and information disseminated by Defendants, which included Defendants' omissions of material facts in which Plaintiff had no way to know were omitted.

106. Plaintiff justifiably relied on Defendants' material misrepresentations, including the omissions contained therein, when making the decision to accept, purchase and/or consume Ozempic.

107. Had Plaintiff been told of the lack of sufficient and/or appropriate testing of Ozempic for safety risks, including ileus, intestinal obstruction, and their sequelae, Plaintiff would not have used Ozempic and/or suffered ileus, intestinal obstruction, and their sequelae.

108. As a direct and proximate result of the above stated false representations and/or omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries including ileus, intestinal obstruction, and their sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

109. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or

hospital care, attention, and services.

FOURTH CAUSE OF ACTION
(FRAUDULENT CONCEALMENT —AGAINST ALL DEFENDANTS)

110. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

111. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Ozempic, which were used by Plaintiff as hereinabove described.

112. At all relevant times, Defendants knew or should have known that Ozempic had not been adequately and/or sufficiently tested for safety.

113. Defendants had a duty to disclose material information about Ozempic to Plaintiff and Plaintiff's prescribing physician(s), namely that Ozempic are causally associated with increased risks of ileus, intestinal obstruction, and their sequelae, because Defendants have superior knowledge of the drugs and their dangerous side effects, this material information is not readily available to Plaintiff or Plaintiff's prescribing physician(s) by reasonable inquiry, and Defendants knew or should have known that Plaintiff and Plaintiff's prescribing physician would act on the basis of mistaken knowledge.

114. Nonetheless, Defendants failed to execute their duty to disclose these material facts. Defendants consciously and deliberately withheld and concealed from Plaintiff's prescribing physician(s), Plaintiff, the medical and healthcare community, and the general public this material information.

115. Although the Ozempic label list nausea, vomiting, diarrhea, abdominal pain, and constipation as common adverse reactions reported in Ozempic patients, they do not mention ileus

and intestinal obstruction as risks of taking Ozempic, nor do they identify ileus and intestinal obstruction as chronic conditions that can result as a consequence of taking Ozempic.

116. Defendants' promotional websites for Ozempic similarly do not disclose that Ozempic are causally associated with increased risk of ileus, intestinal obstruction, and their sequelae.

117. Defendants' omissions and concealment of material facts were made purposefully, willfully, wantonly, and/or recklessly in order to mislead and induce medical and healthcare providers, such as Plaintiff's prescribing physician(s), and adult type 2 diabetes patients, such as Plaintiff, to dispense, provide, prescribe, accept, purchase, and/or consume Ozempic for treatment of type 2 diabetes.

118. Defendants knew or should have known that Plaintiff's prescribing physician(s) would prescribe, and Plaintiff would use Ozempic without the awareness of the risks of serious side effects, including ileus, intestinal obstruction, and their sequelae.

119. Defendants knew that Plaintiff and Plaintiff's prescribing physician(s) had no way to determine the truth behind Defendants' misrepresentations and concealments surrounding Ozempic, as set forth herein.

120. Upon information and belief, Plaintiffs prescribing physician(s) justifiably relied on Defendants' material misrepresentations, including the omissions contained therein, when making the decision to dispense, provide, and prescribe Ozempic.

121. Upon information and belief, had Plaintiff's prescribing physician(s) been told that Ozempic had not been sufficiently and/or adequately tested for safety risks, including ileus, intestinal obstruction, and their sequelae, they would not have prescribed Ozempic and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Ozempic to allow Plaintiff to make an informed decision regarding Plaintiff's use of Ozempic.

122. Plaintiff justifiably relied on Defendants' material misrepresentations, including the

omissions contained therein, when making the decision to purchase and/or consume Ozempic.

123. Had Plaintiff been informed of the increased risks causally associated with Ozempic, Plaintiff would not have used Ozempic and/or suffered ileus, intestinal obstruction, and their sequelae.

124. Defendants' fraudulent concealments were a substantial factor in causing Plaintiff's injuries.

125. As a direct and proximate result of the above stated omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries, including ileus, intestinal obstruction, and their sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

126. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of Defendants, who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to Plaintiff in an amount sufficient to punish Defendants and deter

future similar conduct;

3. Awarding Plaintiff the costs of these proceedings; and

4. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all triable issues within this pleading.

Dated: July 31, 2025

Respectfully submitted,

/s/ *Tiffany R. Ellis*

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Attorney for Plaintiff

CERTIFICATE OF SERVICE

I certify that on July 31, 2025, I filed the foregoing document with the Clerk of the Court using the ECF system, which will send notification electronically to all parties of record.

/s/ Veronica L. Stewart
Veronica L. Stewart, Paralegal